

## NOTICE OF REASONS FOR REJECTION

Application Number: Japanese Patent Application No. 10-509546

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Sections Applied: Section 29, main para., Section 29(2)

The captioned application should be rejected for the reasons set forth below. If the applicant wishes to present an argument in response to this notice, however, a written argument should be submitted within three months from the mailing date of this notice.

### REASONS

1. The inventions according to the claims of the present application indicated below are unpatentable under the main paragraph of Section 29(1) of the Patent Law because they do not comply with the requirements of the main paragraph of Section 29(1) of the Patent Law.

2. The inventions according to the claims of the present application indicated below are unpatentable under Section 29(2) of the Patent Law because they could readily have been made by a person skilled in the art prior to the filing of the application on the basis of the inventions disclosed in the herein-cited publications distributed in Japan or abroad prior to the filing of the application.

NOTE (Please refer to List of Cited References for references cited.)

Claims: 1-21

Reason: 1

Remarks:

The invention according to claims 1-21 is a method comprising a step of administrating beta-alanine to a human. Thus, the invention corresponds to a method for operating, treating or diagnosing a human.

Therefore, it is not considered that the invention according to claims 1-21 is an industrially applicable invention.

Claims: 1-24

Reason: 2

Cited references: 1, 2

Remarks:

Cited Reference 1 describes buffering action of hydronium ion concentration with histidine containing protein such as carnosine and anserine in muscle fiber of a human or animal.

Also, cited Reference 1 suggests that the histidine containing dipeptide is involved in resistance to long-term hypoxic condition or adaptability to a bad effect by anoxic condition.

Thus, the invention described in cited Reference 1 differs from the invention according to claims 1-25 in the following respects;

- Cited Reference 1 does not describe that an amount of beta-alanine effective to increase beta-alanylhistidine dipeptide synthesis in tissue is provided to blood or plasma, the tissue is exposed to the blood or plasma, thereby the concentration of beta-alanylhistidine (carnosine) is increased in the tissue.
- Cited Reference 1 does not describe that L-histidine, creatine or insulin is further provided.
- Cited Reference 1 does not describe a composition including a specified amount of beta-alanine, carbohydrate, water and L-histidine.
- Cited Reference 1 does not describe a composition including a specified amount of beta-alanine, water, L-histidine and creatine.

Cited Reference 2 describes that beta-alanine is specifically incorporated into carnosine as shown by previous *in vivo* studies. Cited Reference 2 also describes that beta-alanine taken in nasal cavity is converted to carnosine in the body (see Abstract, Figs. 6 or 7.)

Therefore, a person skilled in the art could readily have conceived of providing beta-alanine (a precursor of carnosine) to the tissue as a buffering agent for hydronium ion concentration in muscle fiber, in order to regulate the concentration of hydronium ion in the muscle fiber or to increase the anaerobic working capacity in the tissue.

Also, a person skilled in the art could have performed providing L-histidine which is another component of carnosine, creatine which is involved in muscle performance ability (see References 3-5), insulin which is involved in acceleration of glucose, amino acid or potassium uptake in skeletal muscle (see Reference 6) together with beta-alanine, as necessary.

Furthermore, a person skilled in the art could have selected a method for providing the aforementioned components to the tissue, for example, provision of the components to blood or plasma, or oral ingestion of the components as a composition including water and carbohydrate which is a source of energy, as necessary.

Therefore, the invention of according to claims 1-24 could readily have been performed by a person skilled in the art based on the descriptions of cited References 1-2 and the common technical knowledge before the priority date of the present application.

#### List of Cited References

1. HARRIS, R.C. et al, Muscle buffering capacity and dipeptide content in the thoroughbred horse, greyhound dog and man, *Comp Biochem Physiol A*, 1990, Vol.97, No.2, p.249-51
2. BURD, G.D. et al, Carnosine in primary afferents of the olfactory system: an autoradiographic and biochemical study, *J Neurosci*, 1982, Vol.2, No.2, p.244-55
3. JP Patent Publication (Kokai) No. 7-236460 A (1995)
4. JP Patent Publication (Kokai) No. 8-224073 A (1996)
5. JP Patent Publication (Kohyo) No. 7-509230 A (1995)
6. The dictionary of Physics and chemistry, Iwanami Shoten, 1987, 4<sup>th</sup> edition, p.90